LABORATORY REPORT

Reg. No	:	**30100200114**	Reg. Date	:	20-Jan-2023 10:34
Name	:	**SUPARNA PAL**	Collected on	:	20-Jan-2023 10:34
Sex/Age	:	**Female / 41 Years**	Approved Date	:	30-Jan-2023 17:44
Ref. By	:		Tele. No	:	9833253102
Location	:	LILAC INSIGHTS PVT. LTD. @ MUMBAI	Dispatch At	:	

Please find detailed report of NGS Oncomine Precison GX Assay (DNA mutations, CNVs, RNA Fusions)(Liquid biopsy) in the following pages.

---------- End Of Report ----------

Neeraj Arora

Dr. Neeraj Arora
M.D (Path), PDF (Mol Haemat),
PDF (Haematopath)
22396

Patient Details

Patient Name	**SUPARNA PAL**	**Sample Id/LabID**	**30100200114**
Gender	Female	**Sample Type**	Peripheral Blood in Streck tube:10ml
DOB/AGE	41 yrs	**Date of Sample Collection**	20/01/2023
Ref.By	LILAC INSIGHTS PVT. LTD.	**Date of Receipt**	20/01/2023
		Date of Report	30/01/2023

NGS Oncomine Precision GX Assay (DNA mutations, CNVs, RNA Fusions)-Liquid Biopsy

Clinical Details:

Diagnosed case of Metastatic Ca lung -B/L lung mets- Adenocarcinoma satge-4 ALK, EGFR, PDL1,Neg, ROS not done.(On treatment)

RESULT

NEGATIVE:

- No Clinically Relevant Pathogenic Mutations Identified.

- No Fusion Identified.

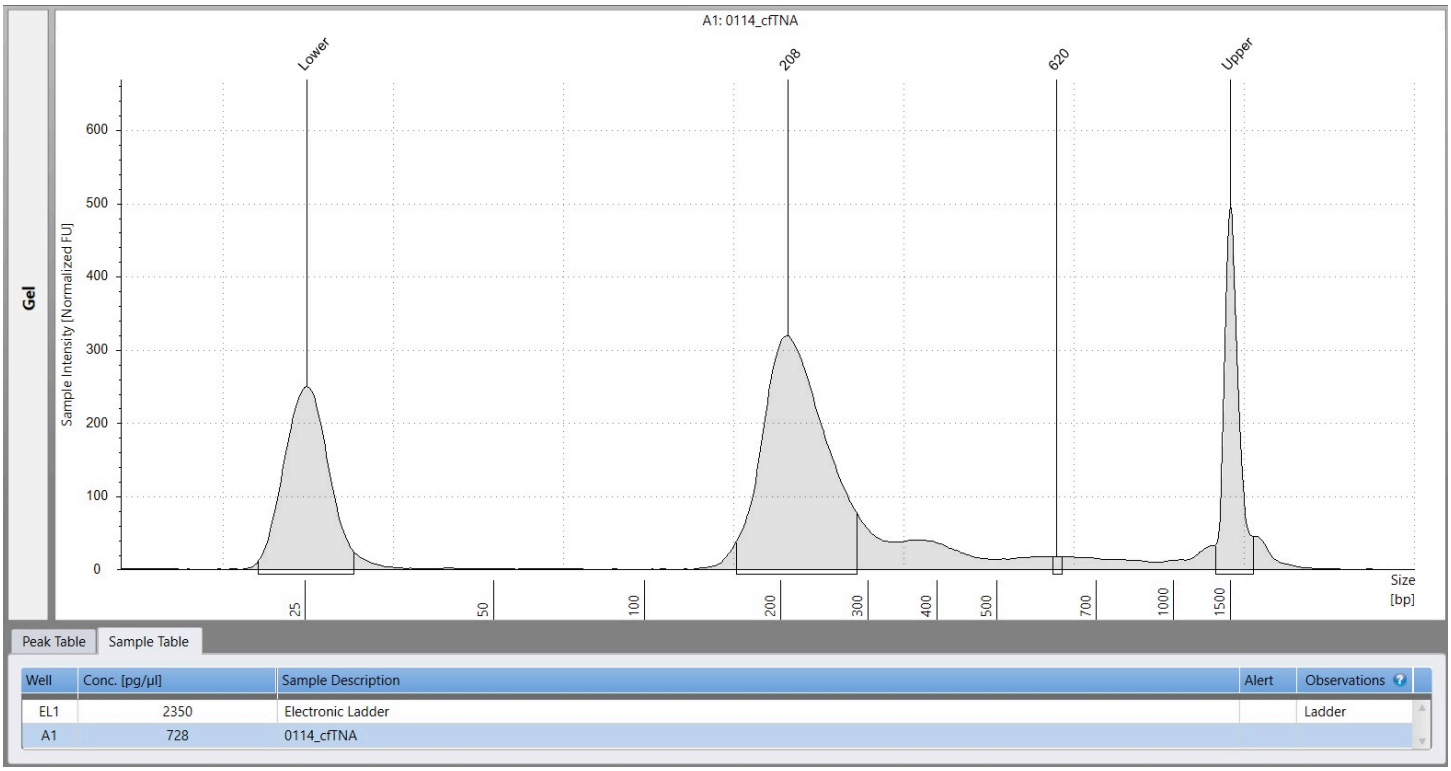
Comments:

These findings should be corelated with other clinical and laboratory tests for a definite conclusive interpretation.

Methodology

Nucleic acid (DNA/RNA) was extracted from provided peripheral blood in streck tube, using Standard Total Nucleic Acid Isolation Kit as per user manual. Automated library preparation and sequencing run was perfomed using Oncomine Precision assay GX on Genexus platform as per user manual. Generated data was analyzed using on board analysis software with default filter chain. Default filter chain is optimized for reporting detected variants with the Oncomine™ Precision Assay GX.This filter chain provides results for INDELs and SNV variant types, and minor allele frequencies between 0.0 and 1.0E-6 based on 5000Exomes and ExAC annotation source databases that have homopolymer lengths less than or equal to 7 and allele frequencies between 0.05 and 1.0.

CfTNA Profile on Tapestation using DNA1000 screen



Run QC statistics
Sample is sequenced at Average base coverage depth of 35,666. The Target base coverage at 500X is 100.0%.

Variant Classification

- **Pathogenic**: The pathogenic variant are the one which is believed to account for the symptoms. It increases an individual's susceptibility or predisposition to a certain disease or disorder. This mutation is always included in results section of report.
- **Likely Pathogenic**: The likely pathogenic variant are the one which most likely have harmful effect but, there is insufficient evidence that a variant is the definite cause for symptoms. This mutation is always included in results section of report
- **Variant of Uncertain Significance**: The Variant of Uncertain Significance (VUS) are the one which have limited and/or conflicting evidence regarding pathogenicity. Its exact effect on gene function is not known. With more information available over time, a VUS may be reclassified as likely pathogenic or likely benign. This mutation is always included in results section of report.
- **Likely benign**: The likely benign variants are the one which are most likely not associated with disease risk. However, additional evidence is needed to confirm this assertion. This mutation is not included in report
- **Benign**: The benign variants are the one which are represented by alteration in gene compare to wild-type allele but it is not associated with disease risk. This mutation is not included in report.

Evidence Based Variant Classification

Tier I	Variants with strong clinical significance	Level A evidence	FDA-approved therapy included in professional guidelines
		Level B evidence	Well-powered studies with consensus from leaders in the field
Tier II	Variants with potential clinical significance	Level C evidence	FDA-approved therapies for different tumor types or investigational therapies. Multiple small published studies with some consensus
		Level D evidence	Preclinical trials or few case reports without consensus.
Tier III	Variants of unknown clinical significance		Not observed at significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases. No convincing published evidence of cancer association

Genes Assayed

Genes Assayed for the Detection of DNA Sequence Variants

AKT1, AKT2, AKT3, ALK, AR, ARAF, BRAF, CDK4, CDKN2A, CHEK2, CTNNB1, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, GNA11, GNAQ, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, NTRK1, NTRK2, NTRK3, PDGFRA, PIK3CA, PTEN, RAF1, RET, ROS1, SMO, TP53

Genes Assayed for the Detection of Copy Number Variations

ALK, AR, CD274, CDKN2A, EGFR, ERBB2, ERBB3, FGFR1, FGFR2, FGFR3, KRAS, MET, PIK3CA, PTEN

Genes Assayed for the Detection of Fusions

ALK, AR, BRAF, EGFR, ESR1, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, NUTM1, RET, ROS1, RSPO2, RSPO3

Limitations and Disclaimer

1. This test was developed and its performance characteristics determined by Unipath Specialty Laboratory Ltd, Ahmedabad. It has not been cleared or approved by the US Food and Drug Administration and NABL.
2. This test is a screening test and enables researchers to develop tests that may impact treatment selection, treatment monitoring, and recurrence monitoring in the future
3. False negative results may be due to sampling issues, errors in sample handling, mislabelling, transportation issues, and technical limitations of the assay and mutations frequency below the limit of detection of the assay, i.e., 0.1% for somatic variants. It is also possible some complex insertion/deletion variants may not be identified.
4. Extreme low circulating mutant cell free DNA leads to false negative result. Therefore in all negative cases, it is recommended to perform retesting on fresh tissue biopsy/tissue block.
5. This test is not intended to detect minimal residual disease.
6. Results of this test need be interpreted within the context of clinical findings and other relevant clinical and laboratory data and should not be used alone.

Report Signed by:

DR. SPANDAN CHAUDHARY, Ph.D
(Sr. Scientist, NGS Division)

DR. EKTA JAJODIA, MD (Path.),
PDF (Mol. Hemat),Consultant Pathologist

DR. NEERAJ ARORA, MD ,
PDF (Mol.Hemat), PDF (Haematopath)
Lab Director